REMARKS

This submission is responsive to the Office Action dated January 2, 2008. Claims 19-33, 35-45, 53-62, 72 and 73 are pending.

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 19-33, 35-45, 53-62, 72 and 73 under 35 U.S.C. § 102(e) as being anticipated by Hatlestad et al. (US 2005/0042589, herein referred to as "Hatlestad"). Applicant respectfully traverses the rejection. Hatlestad fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

Claims 19-33, 35-45, 53-62

Hatlestad fails to disclose or suggest determining a value of a sleep metric that indicates a non-binary probability of a patient being asleep based on physiological parameters, as required by each of independent claims 19, 39 and 59. Although Hatlestad discloses sleep quality metrics, Hatlestad does not disclose or suggest a sleep metric that indicates a non-binary probability of a patient being asleep based on physiological parameters. The sleep quality metrics disclosed in Hatlestad do not indicate a non-binary probability of a patient being asleep, as required by independent claims 19, 39 and 59. Some of the sleep quality metrics are calculated based on the amount of time a patient was asleep, but do not indicate a non-binary probability of a patient being asleep.

With respect to determining whether a patient is asleep, Hatlestad describes making binary determinations of sleep onset and termination by comparing a detected sleep-related condition to a sleep threshold.[1] Hatlestad describes a sleep detection unit including two sensors.[2] A sleep detection sensor detects a first sleep-related condition. The first sleep-related condition is compared to a sleep threshold to detect sleep onset and termination. A threshold adjustment sensor detects a second sleep-related condition that is used to adjust the sleep threshold. Although the value of the sleep threshold changes, the sleep detection unit definitively detects sleep onset and termination. The sleep detection unit does not determine a probability of a

[1] Hatlestad, paragraph [0082].
[2] Hatlestad, paragraphs [0081] and [0082].

patient being asleep. Instead, the sleep detection unit compares a value of the first sleep-related condition to the sleep threshold and makes a binary determination of whether the patient is asleep based on the comparison.

The Office Action cited paragraphs [0135]-[0162] of Hatlestad as teaching a sleep metric that indicates a non-binary probability of a patient being asleep. However, the cited portion of Hatlestad describes a variety of sleep quality metrics, not sleep metrics. The sleep quality metrics described in Hatlestad do not indicate a non-binary probability of the patient being asleep. As one example, Hatlestad teaches that undisturbed respiration sleep time may be calculated by subtracting sleep time in disturbed breathing from the total time asleep. The total time asleep may be determined using the binary sleep detection of Hatlestad discussed above. Hatlestad also describes disordered breathing detection methods that are used to determine sleep time in disturbed breathing.

Neither the undisturbed respiration sleep time, nor the sleep time in disturbed breathing, indicate a non-binary probability of the patient being asleep. In fact, none of the sleep quality metrics described in paragraphs [0135]-[0162] indicates a non-binary probability of the patient being asleep. As previously discussed, Hatlestad describes a sleep detection unit that determines whether the patient is asleep. The sleep quality metrics described in paragraphs [0135]-[0162] quantify the quality of the patient's sleep, and do not indicate a probability of the patient being asleep.

Claims 72 and 73

With respect to independent claim 72, Hatlestad also fails to disclose or suggest an implantable medical device that includes a processor that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors, for each of the plurality of physiological parameters, determines a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a probability of the patient being asleep based on the respective physiological parameter, and mathematically combines the plurality of sleep metric values that each indicate that probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall probability of the patient being asleep.

Similarly, with respect to independent claim 73, Hatlestad fails to disclose or suggest a system comprising means for monitoring a plurality of physiological parameters of a patient, implantable means for determining a respective one of a plurality of sleep metric values for each of the plurality of physiological parameters, each of the sleep metric values indicating a probability of the patient being asleep based on the respective physiological parameter, and implantable means for mathematically combining the plurality of sleep metric values that each indicate the probability of the patient being asleep based on the respective one of the plurality of physiological parameters to determine an overall sleep metric value that indicates an overall probability of the patient being asleep.

The Office Action cited paragraphs [0090]-[0103] as describing a process of determining an overall sleep metric value based on values of a plurality of sleep metrics. As discussed above with respect to independent claims 19, 39 and 59, Hatlestad fails to disclose or suggest a single sleep metric that indicates a probably of the patient being asleep, much less a plurality of such metrics, or determining an overall sleep metric that indicates an overall probability of the patient being asleep based of the plurality of sleep metric values.

The cited portion of Hatlestad discusses an embodiment of the previously described binary sleep detection method that utilizes an activity sensor as the sleep detection sensor and a minute ventilation sensor as the threshold adjustment sensor. In this embodiment, the minute ventilation sensor determines the sleep threshold value, and the patient's activity level is compared to the value to detect sleep onset and termination. The patient's heart rate is also monitored to confirm that the patient is asleep when sleep onset is detected.

Each of the activity level, minute ventilation, and heart rate do not individually indicate a probability of the patient being asleep. Rather, a specific combination of values of these parameters indicate that the patient is in fact asleep (i.e., an activity level below a threshold value determined by the minute ventilation value in combination with a sleep-compatible heart rate). Thus, in Hatlestad, the activity level, minute ventilation, and heart rate are not sleep metric values, because they do not individually indicate a probability of the patient being asleep. Furthermore, the activity level, minute ventilation, and heart rate are not are not mathematically combined to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. Hatlestad does not even discuss determining an overall probability of the

patient being asleep and, instead, describes making a binary determination that the patient is asleep.

Additionally, Hatlestad does not disclose or suggest mathematically combining a plurality of sleep metric values that each indicates the probability of the patient being asleep based on a respective physiological parameter. The minute ventilation is used to adjust the sleep threshold. The threshold value does not indicate a probability of the patient being asleep. The patient's activity is compared to the threshold value to make a binary determination of whether the patient is asleep. If it is determined that the patient is asleep based on the comparison, a second binary determination of whether the heart rate is compatible with sleep is determined. If both binary determinations indicate sleep, sleep onset is confirmed. If the heart rate is incompatible with sleep, minute ventilation and patient activity continue to be monitored. The two determinations of sleep state are not mathematically combined to determine an overall probability of the patient being asleep. Instead, they are compared to provide a binary determination of whether the patient is asleep.

Hatlestad fails to disclose each and every limitation set forth in claims 19-33, 35-45, 53-62, 72 and 73. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 19-33, 35-45, 53-62, 72 and 73 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Application Number 10/825,964
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Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 4-2-08

By: _____

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